

OCT 17 2002

A COMPANY OF THE  
OTTO BOCK GROUP

**510(k) SUMMARY  
of  
SAFETY and EFFECTIVENESS**

**A. General Information**

1. *Submitter's Name:* Otto Bock Health Care, Inc.
2. *Address:* Two Carlson Parkway N., Suite 100  
Minneapolis, MN 55447-4467
3. *Telephone:* 763-553-9464
4. *Contact Person:* E.P. (Bert) Harman
5. *Date Prepared:* August 14, 2002
6. *Registration Number:* 2182293

North American Headquarters  
Two Carlson Parkway N., Suite 100  
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Toll-free Fax 1-800-962-2549  
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Technical Center  
14800 28<sup>th</sup> Avenue North, Suite 110  
Minneapolis, MN 55447-4873  
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Toll-free 1-800-795-8846  
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Toll-free Fax 1-800-810-7994  
[www.ottobockus.com/services](http://www.ottobockus.com/services)

**B. Device**

1. *Name:* Sherpa Mobility System  
(Manual Wheelchair)
2. *Trade Name:* Sherpa Mobility System  
(Manual Wheelchair)
3. *Common Name:* Manual Wheelchair
4. *Classification Name:* Manual Wheelchair
5. *Product Code:* IOR
6. *Class:* I
7. *Regulation Number:* 890.3850

Customer Support &  
Distribution Center  
14630 28<sup>th</sup> Avenue North  
Minneapolis, MN 55447-4821  
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Toll-free 1-800-328-4058  
Fax 763-519-6150  
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Design & Manufacturing Center  
3820 Great Lakes Drive  
Salt Lake City, UT 84120-7205  
Phone 801-956-2400  
Fax 801-956-2401



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 17 2002

Otto Bock Healthcare  
E. P. (Bert) Harman  
CEO/President  
2 Carlson Parkway, North  
Suite 100  
Minneapolis, Minnesota 55447-4467

Re: K022924

Trade/Device Name: Sherpa Mobility System (Manual Wheelchair)  
Regulation Number: 890.3850  
Regulation Name: Wheelchair, mechanical  
Regulatory Class: Class I  
Product Code: IOR  
Dated: August 14, 2002  
Received: September 4, 2002

Dear Mr. Harman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

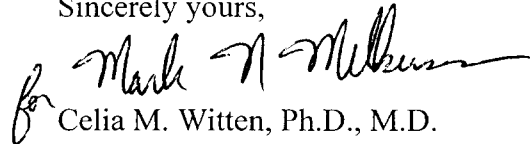
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. E. P. (Bert) Harman

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number: *To be determined*

Device Name: Sherpa Mobility System (Manual Wheelchair)

Indications for Use:

- Manual transportation device for person who are unable to walk or have a walking impediment, propulsion by an attendant.

PLEASE DO NOT WRITE BELOW THIS LINE –  
CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

OVER-THE-COUNTER USE ✓  
(optional Form 1-2-96)

*for Mark N. Miller*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative  
and Neurological Devices

510(k) Number K022929